Human Health Report for
Case # P-17-0382

Report Status:
Complete

Status Date:
09/01/2017

CRSS Date:
08/31/2017

SAT Date:
09/01/2017

Health Assessor: Babcock, Amy

Consolidated PMN?:
N

Ecotox Related Cases:

Human Health Related Cases: [redacted]

SAT
Chair: K.Moran

CBI: [redacted]

Submitter:
Chemtura Corporation

CAS Number: 1454803-04-3

Chemical Name: Amides, tallow, N,N-bis(2-hydroxypropyl)

Use:
Friction modifier
for motor oils lubricants, mainly used in passenger vehicles. [redacted]

Trade Name: MLA-3202, Naugalube® OFM 3202	**PV - Max(Kg/Yr):** [redacted]

Physical Chemical Information

Molecular Weight: 397.65	**Physical State - Neat:** Liquid
Wt% < 500:	**Wt% < 1000:**
Melting Point (Measured): -50.00 - 10.00	**Melting Point (est):**
Boiling Point (Measured):	**Boiling Point (est):** Dec. ca. 200
Vapor Pressure:	**Vapor Pressure (est):** < 0.000001
Water Solubility: 0.000540	**Water Solubility (est):**
Log Kow:	**Log P:**
pH and/or pKa:	**Log P:**

Nanomaterial?

Percent of other substances in PMN formulation:

P2 Rec:

P2

Claims: The customer will transfer additive fluid from a drum at room temperature by using a pump or applied vacuum to a suitable wand inserted into the drum to pull out the additive as required (figure attached). By using this method as the drum is near empty it can be tilted to remove much more of the additive leaving virtually no heel at the bottom and only material that has wetted the sides of the drum. The empty drums must be handled appropriately in-line with legal requirements. Options include

washing with a suitable minimum amount of the standard drum cleaning solvent system and the rinse disposed of as hazardous material by incineration, kept by the customer for their own additional uses possibly to contain the finished product fully blended motor oil, shredding and disposal in a secure hazardous waste landfill, or once clean the drums are crushed and disposed of by sending to a recycled facility as metal waste. For bulk liquid containers (i.e. tank trailers) a pump or nitrogen pressure is used to empty the bulk liquid containers. The containers are then cleaned at an approved wash terminal and the wash liquid disposed of as a hazardous waste. A Diagram of potential setup- for process of adding our MLA-3202 friction modifier to blending tank formulation of a final customer passenger car motor oil is represented in the attached document. It is expected that nearly all of the notified substance will be blended into passenger vehicle motor oils in contained industrial facilities. Occupational exposure may occur during blending activities; however, this exposure is expected to be minimized using engineering controls and personal protective equipment. Occupational exposure to the motor oils containing the notified substance is expected to include workers who manufacture passenger vehicles (i.e. OEMs), and those who change motor oils in commercial automotive repair facilities (i.e. Mr. Lube, Canadian Tire, etc.). Exposure in occupational settings is expected to be minimized using personal protective equipment and engineering controls. Finished motor oils are expected to be available to the consumer through retail establishments; however, these products are not intended to be used on a frequent basis. It is estimated that the frequency of do-it-yourself (DIY) oil changes would be 2-3 times per year, and these DIY activities would not be conducted by significant portion of the population. Public exposure to the notified substance is expected to be negligible. Consumers will not be expected to handle the neat product. Disposal of the final formulated lubricant must be carried out according to best practice for motor oil, for example, many municipal recycling centers have used-oil disposal stations. Utilize a designated oil-disposal facility to avoid incorrect -- and in most cases illegal -- disposal methods. Never dispose of used motor oil in the trash, down household drains, into storm drains or directly onto soil. Inspecting equipment and vehicles regularly and immediately repairing items that appear to be leaking oil is another way to prevent pollution from used motor oil:
http://www.fwpcoa.org/content.aspx?
page_id=2507&club_id=859275&item_id=1105&pst=3324.
Products containing the notified substance are expected to be blended in contained industrial facilities. Any waste material, including that from an accidental spill, is expected to be collected for recycling or disposal by an approved waste management company. The notified substance may be used in commercial applications in facilities that are expected to be fully contained. Any waste material, including that from an accidental spill, is expected to be collected for recycling or disposal by an

approved waste management company. Consumers are encouraged to dispose of spent oils and lubricants through local municipal hazardous waste programs; however, it is possible that products containing the notified substance (including residue in containers) may be released to land via disposal in regular household waste or in the event of an accidental spill. Consumers will not be expected to handle the neat product. Additionally, the notified substance is inherently biodegradable. Significant release to the environment is not expected when recommended practices are followed.

SAT P2
RecComments:

SAT Concern Level:

Chemical Category:

Health Rating (1): 2 **Health Rating Comment (1):**

Health Rating (2): **Health Rating Comment (2):**

Dermal: Y	**DW:** Y	**Inh:** Y

Other Description (e.g., Ingestion):

Routes of Exposure: Dermal
Drinking Water Inhalation

Health Comments:

Exposure Based Review (Health): [redacted]

Exposure-Based Testing:

SAT Keywords:

SENS; DEVEL; SPLEEN; LIVER; THYROID; AQUATOX.

PBT Ratings:

Persistence	Bioaccumulation	Toxicity	Comments
3	1	2	

Fate Information:

Health Summary:

Absorption is poor- moderate through skin, poor through lung, and moderate through the GI tract (pchem). Uncertain concern for sensitization based on conflicting study results provided by the submitter and positive skin sensitization data for the analog [redacted]; further assessment is needed. Uncertain concern for spleen and liver toxicity based on a submitted repeated dose study; further assessment is needed. Uncertain concern for developmental toxicity based on a submitted developmental and reproduction toxicity test and uncertain developmental neuro concerns based on data for [redacted] with reported thyroid gland hyperplasia following dermal exposure to mice.There is a marginal concern for oncogenicity based on [redacted], where one analog was reported to be positive after dermal administration and the other analog was equivocal. There is concern for irritation to all tissues, and lung effects if inhaled based on the surfactant properties of the PMN material.

Test Data Submitted:

Test data submitted with PMN:
(-) Salmonella and E.coli
gene mutation assay with and without activation;
(-) chromosomal aberrations
assay in peripheral human lymphocytes with and without activation;
(-) gene
mutation assay in L5178Y mouse lymphoma cells with and without activation;

(-) in vitro skin corrosion assay in reconstructed human epidermis;
(-)
in vitro skin irritation in reconstructed human epidermis;
(-) skin
irritation, rabbits;
(-) eye irritation based on an in vitro bovine corneal
opacity and permeability test;
(-) eye irritation, rabbits;

(+) skin
sensitization, local lymph node assay;
(-) skin sensitization, Buehler skin
sensitization assay;
acute oral LD50 > 5000 mg/kg-bw, rat;
acute
dermal LD50 > 5000 mg/kg-bw, rat;
28-day oral repeated dose study with a
NOEL of 300 mg/kg bw and a NOAEL of 1000 mg/kg-bw based on reduced spleen weights with the absence of hematopoiesis and hepatocellular hypertrophy (submitter claimed non-adverse, further review needed);

reproduction/developmental toxicity test with a NOAEL of 1000 mg/kg-bw (highest dose tested) as stated by the submitter, but noted maternal toxicity was reported at 300 mg/kg bw and greater and a complete litter loss was reported at 1000 mg/kg bw (further review needed);

Comments and/or Telephone Log:

Artifact	Update/Upload Time